

REMARKS

Status of Claims

Claims 1 - 16 are present for examination. and in the Examiner's paper mailed

5 02/06/08,

The response on 04/21/08 in the co-pending case included a Terminal Disclaimer for the subject case as a related case and that disclaimer was entered on 05/08/08.

10 At page 5, Item 3. of the subject Examiner's Office Action mailed 02/06/08, the Examiner rejects claims 1 - 15 on the "ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1 - 11 of co-pending 10/414,796 filed 04/16/2003.

15 Four inventors are listed on the subject Application No. 10/735,451.

Inventors Joe Bango and John B. Fenn are common to both applications.

Bango and Dr. John B. Fenn are the only inventors on the earlier filed 10/735,451
20 application.

Bango has provided a declaration executed on 06/04/08 under 37 C.F.R. 1.132 in which he indicates that inventions disclosed but not claimed in the co-pending application was derived from the inventor of this application and is thus not the invention of another.

25 Bango's declaration is attached to this response and says that:

"inventions disclosed but not claimed in the co-pending application were derived from the inventor of this application and is thus not the invention of another".

30 A first Assignment transfers ownership of 10/414,796 to Ocugenics , LLC on 02/12/08 is found at Reel/Frame 020506/0827.

A second Assignment transfers ownership of 10/735,451 to Ocugenics , LLC on 02/12/08 is found at Reel/Frame 020501/0712. The applications are commonly owned by Ocugenics, LLC.

- 5 In view of the above points, Applicant requests that the Examiner withdraw the rejections of item 3 and 4 on pages 5 and 6 of the Examiner's paper and in view of the facts that the terminal disclaimer of record ends the term of this patent at the same time as the earlier application.
- 10 A Declaration of Dr. Gary Wnek is now included with this AMENDMENT IN RESPONSE TO OFFICE ACTION MAILED 02/06/08. Dr. Wnek is a co-inventor in Simpson et al, US patent Publication 2002/0090725, art cited by the Examiner, and was the team research leader at Virginia Commonwealth University when the Simpson et al work was performed. Dr. Wnek is an expert in polymer research and electrospinning.
- 15 Dr. Wnek's declaration clarifies the following points for the Examiner about the Simpson reference.
1. Simpson et al developed electrospinning of collagen and other polymers for the purpose of encouraging neo-vascularization and cellular ingrowth for the purpose of
 - 20 creating a cellular scaffold, conditions detrimental to an optically clear material as disclosed in the present application.
 2. The electrospinning of Simpson et al was larger than 100 nanometers, the goal of which was NOT optical transparency.
 3. The electrospinning of Simpson et al did not require precise control over fibril
 - 25 diameter, as disclosed in the present subject invention using Alternating Current or AC.
 4. Ultraviolet light and/or radiation was employed in Simpson et al for the purpose of polymer cross linking and/or sterilization, not to neutralize electrical charge.
 5. Reference to use of a plasma to produce ions to neutralize a charge on an electrospun fiber produces high temperatures which could denature collagen and other polymers,
 - 30 and yields ozone which ma further destabilize collagen.

6. A microprocessor was employed in Simpson et al to direct the angle, distance, and voltage of the tip of the needle with respect to the target, yielding a fixed voltage once activated. The microprocessor was not used to an AC rather than a DC potential.

7. The goal of Simpson et al was not to produce optically clear material as is disclosed
5 by the subject invention.

At page 3, paragraph 3 of the Examiner's paper, the Examiner has rejected Claims 1 - 16 under Simpson, et al US 2002/0090725 and Burgess et al, US 6,559, 119 and Noakes in view of Burgess et al, 5,222,663 under 35 U.S.C. 103(a).

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At page 3, at the paragraph beginning with "Claims 1 - 15 are rejected under ---" the Examiner directs the reader to see Simpson et al at paragraphs 147, 204, 209 for a disclosure of making "corneal tissue". With respect, the Examiner is mistaken or possibly the search was performed not by the Examiner but by another less familiar
15 with the case. The following is offered in support of this traverse.

The published version of the Simpson document was called up using a PTO search and the txt version was searched for the phrase "corneal tissue" with no hits. Then the Simpson document was searched for "corneal" and no hits were obtained. Then the
20 Simpson document was searched for the word "cornea" and hits were obtained in the paragraphs recited by the Examiner. However, the paragraphs viewed for the occurrences of the word cornea, found the term contained in a comprehensive listing of parts of the body, the cornea being one of many, but there being no teaching relating to "corneal tissue" as asserted by the Examiner in any of the paragraphs listed.

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Further down the page the Examiner says that "Simpson et al clearly envisioning the formation of corneal tissue that would have to be transparent to be useful ..." and once again, the applicant points out that Simpson never mentions "corneal tissue" but only uses the term of "cornea" when listing as many body parts or systems as the drafting
30 attorney could probably find in a summary list of such components. The inclusion of the term "cornea" is listed with other parts like "heart valve" and it may be appropriate

in view of the structural repair and support purpose that the Simpson material was being made for. However, the Simpson reference does not mention nor does it teach anything about “corneal tissue”. There is not teaching in Simpson as asserted by the Examiner that

5 “Simpson et al clearly envisioning the formation of corneal tissue that would have to be transparent to be useful ...”, .

That view is supported by the declaration of Dr. Wnek, an expert in the field, with knowledge of the facts, in his statements to the Examiner at the Examiner’s interview
10 mentioned below, and in Wnek’s declaration, a copy of which is attached to this response..

On 02/14/08 an Examiner’s Interview was conducted at the USPTO for the purpose of discussing the 10/414,796 case and this related case S/N 10/735,451. Those present
15 included Inventors J. Bango, and Randall Fuerst. Examiner R. T. Niebauer and M. Vargot were present. SPE Anish Gupta attended. James F. Kirk appeared as patent attorney for the clients present. J. Bango is an inventor named on the subject application along with Dr. John B. Fenn, a Nobel laureate. Randall Fuerst is named as an inventor on the S/N 10/735,451 case.

20 Dr. Gary Wnek appeared for the purpose of explaining, as an actual inventor on the Simpson reference US 2002/0090725, what the invention team on that invention knew and what their objectives were. Wnek explained that the Simpson team had no intention of developing material that was optically transparent.

25 Dr. Wnek has provided a re-executed declaration for submission as evidence in the 10/414,796 case and a copy of that declaration is submitted for the same purpose herewith. The declaration is 27 pages in length. The most relevant pages relating to the Examiner’s rejection are at pages 5 - 7. Dr. Wnek has provided his opinions on those
30 pages.

When the Examiner points says on page 3 of his paper that “Simpson et al clearly envisioning the formation of corneal tissue that would have to be transparent to be useful.” the Examiner’s statement is at odds with the position taken by Dr. Wnek, a co-
5 inventor of the process covered in the Simpson reference as pointed out in Dr. Wnek’s declaration, at page 5, copy attached to this Amendment for reference.

At the fourth paragraph on page 5 Wnek says:

---“Our team had no interest in and to my knowledge never thought about removing the
10 charge from the electrospun fibers as the electrohydrodynamic instability cited in the Bango application does not present itself as a problem in the application of tissue scaffolds.” “In our work, we had no interest in making electrospun collagen fibers optically clear.”

15 The Wnek declaration goes on to assert that “the need for AC voltage was not necessary nor contemplated for the scaffolding application taught in the Simpson publication” and later that ultraviolet light was used in Simpson to promote polymer cross linking of fiber sterilization.” “Ultraviolet light was not used in the Simpson process taught in the Simpson publication to remove any charge buildup or the spun fiber.”

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The independent claims in the subject application are now 1, 13 and 14. Each of the independent claims now contain an amended step h. with limitations as follows:

25 h. moving the needle in a linear direction for a fixed distance and then reversing such motion with respect to the target while at the same time indexing the target utilizing a precision positioner and when the desired pattern has been achieved in one axis, the target is rotated ninety degrees and the process repeated, to provide desired patterns over a region of the target exceeding the perimeter of the contact lens to be
30 formed, depositing the electrospun material as a mat, and

Support for the changes to step h. above is found in the publication US 2005/0067287 A1 of the subject application at paragraph 0029, lines 12 and subsequent.

At the bottom of page 4 and top two lines of page 5, the Examiner's paper, the
5 Examiner rejects the claims under 35 USC 103 under Simpson, et al., US-2002/0090725 and Burgess et al., US-6,559,119.

Claim 36 in Burgess, et al. reads (36. The method of claim 1 or 2, wherein said
biomedical material is selected from the group consisting of an orthopedic device, a
10 urinary catheter, an intravascular catheter, a suture, a vascular prosthesis, an intraocular lens, a contact lens, a heart valve, a shoulder replacement device, an elbow replacement device, a hip replacement device, a knee replacement device, an artificial heart, a fixation plate, a dental implant, a nasal implant, a breast implant, a testicular implant, a sponge, a film and a bag.)

15 The claims in the subject application at claim 1 (As Presently Amended) however are to a "A method of creating a transparent [[permeable]] permeable contact lens from a mat of polymer material formed of strands that exhibits the transparency and diffusion characteristics of corneal stromal tissue .

20 At Burgess claims 1 claims 1. Burgess claims A method of preparing a biomedical device intended for implantation into an animal's body and having a supplemented tissue sealant.

25 This method and process involves tissue sealant. Thus, while a tissue sealant could be added to the surface of a contact lens (as noted in claim 36), the manufacture of a contact lens using the novel approach of utilizing a solvent to dissolve the contact lens material, and then electrospinning this material into a super-porous mat for lathe cutting and/or laser edging is dramatically different and is not suggested nor taught by Burgess.
30 nor Simpson because neither of those applications is required to produce a transparent [[permeable]] permeable contact lens from a mat of polymer material formed of strands

that exhibits the transparency and diffusion characteristics of corneal stromal tissue . as required by the independent claims 1, 13 and 14 in this application. .

At page 7 of the Examiner's paper the Examiner applies the Noakes reference with
5 Simpson to reject the claims under 35 USC 103.

The Noakes reference US 5,222,663, at column 2, line 50, teaches that the preferred switching frequency is one cycle per second. And later in Noakes, note that at column 1 lines 60 – 68 and column 2 lines 1- 7, Noakes teaches that 60 Hz is so high that it will
10 prevent his process from working. Noakes is therefore teaching away from “alternating high frequency voltage electric field” because 60 Hz is not generally considered high frequency and Noakes teaches that even 60 Hz is too high.

Noakes is deals with clouds of droplets in the painting arts launched by pressure toward
15 a target some inches away and not with collagen formed from a Taylor cone in the medical arts attracted to a target by an electric field a few thousandths of an inch away. The class of the Noakes is far afield from that of electrospinning. Noakes may arguably be said to be in a field of non-analogous art as well as the fact that the reference is teaching away from the claimed invention. The Noakes invention solves the problem
20 of getting paint to spread and stick to a target and not be repelled by an electric charge on the target.

The application provides support for “high frequency” at paragraph 0030 line 5 of the 287 publication.

25 Applicant has no knowledge of new matter being added.

The claims as now amended and presented are believed to be in condition for allowance and early allowance is requested. If issues exist that the Examiner feels he would like to discuss with the applicant, the Examiner is invited to feel free to call the applicant at
30 his office number below at any time.

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06/20/08

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PATENT

DOCKET JB0602

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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:Date 06/20/08

Re: The Application For:

FABRICATION OF IMPROVED CONTACT LENS UTILIZING**POLYMER ELECTROSPINNING**

Dear Sir:

15

CERTIFICATE OF MAILING

I hereby certify that this paper (along deposited with the United States with any referred to as being attached or enclosed) is being electronically forwarded to the USPTO EBC on the date shown below via electronic filing to . and mailed using Express Mail with sufficient postage as in an envelope addressed to the : Commissioner of Patents and

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Express Mail Receipt No. **EB 512852256 US****AMENDMENT OF 15 PAGES****REQUEST FOR CONTINUING EXAMINATION**

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PETITION FOR ONE MONTH EXTENSION OF TIME (1.136a)**MAILING CERTIFICATE 37 CFR 1.10****CHECKS FOR \$405,****Return Post Card listing express mail number and contents etc****James F. Kirk**

30

Type or print name of person mailing paper

Date: ~~June 6, 2008~~ **JUNE 20, 2008***James F. Kirk*

(Signature of person mailing paper, James F. Kirk)